

REMARKS / ARGUMENTS**I. Status of the Claims**

Claims 1-20 are pending in this application, of which, claims 6-17 are withdrawn from consideration. Claims 1-5 and 18-20 currently stand rejected. Claims 1 and 20 have been amended herein. The amendments are supported by the specification as filed and do not introduce new matter.

II. Claim Objections

Claim 20 is objected to under 35 U.S.C. § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

While Applicants disagree with this objection, in the interest of compact prosecution, Applicants have herein amended Claim 20 to more explicitly limit the subject matter of the previous claim. Applicants believe that this amendment resolves Examiner's concerns and respectfully request the withdrawal of this objection.

III. Rejections of Claims under 35 U.S.C. § 102(b)

Claims 1-4 and 18-20 are rejected under 35 U.S.C. § 102(b) as being anticipated by Truitt et al, US Patent No. 5,910,252 ("Truitt"). With respect to these rejections, the Office Action states:

With respect to claim 1: Truitt discloses a method of collecting a biological fluid comprising the following steps: collecting a biological fluid, namely blood, by natural flow without a pump (Col. 3, lines 54-57); measuring a fluid flow rate of the biological fluid via scales 92 (Col. 6, lines 10,11); pumping preservation solution in the form of replacement fluid from a reservoir 68 via third pump 66 to the collected biological fluid, necessarily at a solution flow rate (Col. 5, lines 29-31); wherein measuring a fluid flow rate of the biological fluid comprises weighing the collected fluid via scales 92, the pumped preservation solution (already in the collected fluid container) and any preservation solution remaining in the reservoir via scale 72 and the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected fluid and the preservation solution. (Col. 6, lines 33-50)

With respect to claim 2: The method disclosed by Truitt further comprises collecting the blood/biological fluid in a collection bag

86 (Col. 5, line 61 - Col. 6, line 3); pumping the preservation solution to the bag 86 via primary circuit 38 and primary chamber 44 (Col. 5, lines 31-37, Col. 5, line 67 - Col. 6, line 3), wherein the solution flow rate is adjusted while collecting the biological fluid based upon the measured fluid flow rate to preserve a selected ratio between the collected fluid and the preservation solution. (Col. 6, lines 33-50)

With respect to claim 3: The biological fluid disclosed by Truitt comprises blood. (Abstract)

With respect to claim 4: Truitt discloses measuring actual flow rate of the collected fluid via scales 92, and the flow rate and weight of preservation solution remaining in bag 68 via scale 72 but does not explicitly disclose calculating a variation in weight of the collected fluid, the pumped preservation solution and any preservation solution remaining in reservoir 68. However one of ordinary skill in the art could readily and easily perform this step by observing the readout on scales 72 and 92 and either mentally determining the difference in weight or by using a mathematical aid. Therefore it would be obvious to one of ordinary skill in the art to modify the method of Truitt such that the step of measuring a fluid flow rate of the biological fluid further comprises calculating a variation in weight of the collected fluid, pumped preservation solution (already in the collected fluid) and any preservation solution remaining in the reservoir with a reasonable expectation of success to properly discern whether or how much preservation solution is needed or desired.

With respect to claim 18: Truitt discloses collecting the biological fluid with a collection device, namely catheter 33, in fluid communication with the collection bag 86 via a tube in the form of collection line 82 and detecting the presence of the biological fluid in the tube via leak detector 85. (Col. 6, lines 12-15)

With respect to claim 19: Truitt discloses that detecting the presence of the biological fluid, blood, in the tube 82 by leak detector 85 comprises optical sensing. (Col. 6, lines 12-15)

With respect to claim 20: The method of Truitt further discloses collecting a sample of the biological fluid by natural flow without a pump. (Col. 3, lines 54-57)

Office Action at pages 3-5. Applicants respectfully disagree with these rejections.

To form a basis for a § 102(b) rejection, a prior art reference must disclose each and every element as set forth in the claim. See MANUAL OF PATENT EXAMINING PROCEDURE (“MPEP”) § 2131 (2007). “The identical invention must be shown in as complete detail as it is contained in the claim.” *Id.* “The elements must be arranged as required

by the claim.” *Id.* With regard to independent claim 1, *Truitt* fails to disclose every element of the claim.

Specifically, *Truitt* does not disclose, at least, collecting a biological fluid by natural flow, without a pump, as required by independent claim 1. Rather, in *Truitt*, the biological fluid is collected due to first pump 52 and not by natural flow. *Truitt* col. 4, lines 25-35. Hence, *Truitt* fails to disclose the limitation of collecting a biological fluid by natural flow, without the use of a pump. As such, *Truitt* does not disclose each and every limitation as set forth in independent claim 1.

Moreover, *Truitt* does not disclose measuring a natural flow fluid flow rate of the biological fluid, as is also required by amended independent claim 1. On the contrary, according to *Truitt*, the fluid flow rate of the biological fluid is not measured, but it is predetermined in advance. *Truitt* figure 2 and col. 12, lines 27-55. The fluid flow rate through *Truitt*’s system is controlled by pump 52. *Truitt* col. 4, lines 24-26. While *Truitt* may disclose measuring an “actual fluid flow rate” (*Truitt* col. 6, line 9), this flow rate is influenced by, at least, pump 52 (*Truitt* col. 4, lines 25-35) and pump 84 (*Truitt* col. 5, line 67 – col. 6, line 3), and, therefore, is not a natural flow fluid flow rate. Hence, *Truitt* fails to disclose the limitation of measuring a natural flow fluid flow rate of the biological fluid. As such, *Truitt* does not disclose each and every limitation as set forth in independent claim 1.

Additionally, *Truitt* does not disclose adjusting the fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation solution, as is also required by independent claim 1. Rather, the Office Action cites *Truitt* column 6, lines 33-50, which only discloses using a computer to control the operation of the pumps. More generally, in *Truitt*, the solution flow rate is not adjusted to preserve a selected ratio between blood and anticoagulant. *Truitt* col. 5, lines 15; col. 12, lines 27-55. In fact, a diligent search of *Truitt* reveals no discussion of a ratio between the collected biological fluid and any solution whatsoever. Hence, *Truitt* fails to disclose the limitation of adjusting the fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation. As such, *Truitt* does not disclose each and every limitation as set forth in independent claim 1.

Accordingly, Applicants submit that *Truitt* cannot be used to anticipate Applicants’ claims as set forth in independent claim 1. The remaining claims rejected as

anticipated by *Truitt* under 35 U.S.C. § 102(b) depend either directly or indirectly from independent claim 1. Accordingly, Applicants respectfully request withdrawal of this rejection with respect to claims 1-4 and 18-20.

IV. Rejections of Claims Under 35 U.S.C. § 103

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over *Truitt* in view of O'Riordan et al., EP 583,148 A2 ("O'Riordan"). With respect to these rejections, the Office Action states:

With respect to claim 5: Truitt discloses that the step of pumping comprises using a pump having a variable rotation speed inasmuch as the output of the pump is altered by control Application/Control signals. ('252, Col. 6, lines 35-44) However, Truitt does not explicitly disclose that the step of pumping comprises using a peristaltic pump having a variable rotation speed. The method taught by O'Riordan comprises a step of pumping anticoagulant, wherein the act of pumping comprises pumping using a peristaltic pump 42 having a variable rotation speed, inasmuch as the minimum pump speed can be set and the operation of the pump is controlled to ensure maintenance of the desired flow rate of anticoagulant. ('148, Page 3, lines 54, 55; Page 5, lines 4,5) Since the prior art of O'Riordan seeks to solve a similar problem in the art to that with which applicant is concerned it would be obvious to one of ordinary skill in the art to modify the method of Truitt such that the step of pumping comprises using a peristaltic pump having a variable rotation speed as disclosed by O'Riordan with a reasonable expectation of success to allow changes in blood or preservation solution flow rate to ensure proper physiological balance for the patient.

Office Action at pages 5-6. Applicants respectfully disagree with these rejections.

The examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP § 2142. The examiner must show that the claimed invention "as a whole" would have been obvious to a person of ordinary skill in the art when the invention was unknown and just before it was made. *Id.* The showing must be made on the basis of the facts gleaned from the prior art without resorting to hindsight based upon applicant's disclosure. *Id.* All of the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR International Co. v.*

Teleflex Inc., 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007) quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006).” MPEP § 2143.01.IV.

The Office Action fails to state a *prima facie* case of obviousness. As previously discussed, *Truitt* fails to disclose, at least, collecting a biological fluid by natural flow, without a pump, measuring a natural flow fluid flow rate of the biological fluid, or adjusting the fluid flow rate to preserve a selected ratio between the collected biological fluid and the anticoagulant and/or preservation, as required by independent claim 1. *O'Riordan* fails to obviate the deficiencies of *Truitt*. For example, *O'Riordan* does not disclose, at least, collecting a biological fluid by natural flow, without a pump. Although *O'Riordan* discloses some embodiments which utilize a suction wand (*O'Riordan* p. 3, lines 21-22) and others which utilize a needle (*O'Riordan* p. 3, lines 45-48), the disclosure is explicitly limited to embodiments with a pump: “As embodied herein, the transporting means includes... a pump means such as a peristaltic pump or a vacuum pump for conveying fluid through tubing segment 22” (*O'Riordan* p. 3, lines 25-27). As an illustration, *O'Riordan's* Figure 4 replaces the vacuum pump with a peristaltic pump, but it still collects blood with a pump. *O'Riordan* p. 4, lines 56-58; Fig. 4. Hence, neither *Truitt*, *O'Riordan*, nor the references taken together disclose the limitation of collecting a biological fluid by natural flow, without a pump. The Office Action, therefore, fails to state a *prima facie* case of obviousness. For at least these reasons, Applicants respectfully request the withdrawal of the rejection of claim 5.

V. No Waiver

All of Applicants' arguments and amendments are without prejudice or disclaimer. Additionally, Applicants have merely discussed example distinctions from the cited references. Other distinctions may exist, and Applicants reserve the right to discuss these additional distinctions in a later Response or on Appeal, if appropriate. By not responding to additional statements made by the Examiner, Applicants do not acquiesce to the Examiner's additional statements. The amendments and example distinctions discussed by Applicants are sufficient to overcome the rejections of the claims.

All amendments are made in a good faith effort to advance the prosecution on the merits. It should not be assumed that the claims amended herein were amended for reasons relating to patentability. Applicants reserve the right to subsequently take up prosecution on the

claims as originally filed in this or appropriate continuation, continuation-in-part and/or divisional applications.

Applicants respectfully request that the amendments submitted herein be entered and further requests reconsideration in light of the amendments and remarks contained herein.

VI. Conclusion

In light of the above amendment and remarks, which are supported by the specification, Applicants respectfully request reconsideration and withdrawal of the outstanding rejections. Applicants further submit that the application is now in condition for allowance, and solicit timely notice of the same. Should the Examiner have any questions, comments, or suggestions in furtherance of the prosecution of this application, the Examiner is invited to contact the attorney of record.

Applicants believe that no additional fees are due. However, should the Commissioner deem that any fees are due, Applicants respectfully request that the Commissioner accept this as a Petition therefor and direct that any additional fees be charged to Baker Botts L.L.P. Deposit Account No. 02-0383, Order Number 062908.0115, for payment of associated fees, underpayment of fees, or to credit same with any overpayment of fees that may occur in association with this filing.

Respectfully submitted,



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